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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/708, 352 11/08/00 LEONARD J 02108.0001U2

HM12/1010

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EXAMINER

FORD, V

ART UNIT PAPER NUMBER

1645

DATE MAILED:

10/10/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

<i>Office Action Summary</i>	Application No.	Applicant(s)
	09/708,352	LEONARD ET AL.
Examiner	Art Unit	
Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 November 2000.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 20) Other: _____

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 1-12 in Paper No. 7 filed on September 28, 2001 is acknowledged. Groups II-III are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being to a non-elected invention.

The traversal is on the grounds that Groups I-III are not independent and distinct, therefore the examination of the entire application does not constitute a serious burden. These arguments have been fully considered but are not found to be persuasive for the reasons below:

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct patented inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example as product and method of use, etc., but are capable of separate manufacture, use or sale as claimed, and are patentable over each (see MPEP 802.01). In the instant situation, the inventions of Groups I-III are drawn to distinct inventions which are separate products and methods capable of separate manufacture, use or sale as described in the previous Office Action.

Classification of the subject matter is merely one indication of the burdensome nature of the search. The literature search, particularly relevant in this art, is not co-extensive, because for example, Group I is drawn to a product. Groups II and III are drawn to different methods which require different method steps, parameters and endpoints. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

2. Claims I-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims I-12 are drawn to a vaccine composition, wherein at least one inactivated or attenuated *Mycoplasma bovis* biotypes is selected for the group consisting of biotype A, biotype B and biotype C.

Because it is not clear that cell lines possessing the properties of *Mycoplasma bovis* strains are known and publicly available or can be reproducibly isolated from

nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of the above *Mycoplasma bovis*, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

Applicant's referral to the deposit of *Mycoplasma bovis* disclosed in the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met. If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required. If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809,

assurances regarding availability and permanency of deposits are required.

Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

- (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;
- (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;
- (c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and
- (d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain:

- 1) The name and address of the depository;
- 2) The name and address of the depositor;
- 3) The date of deposit;
- 4) The identity of the deposit and the accession number given by the depository;
- 5) The date of the viability test;
- 6) The procedures used to obtain a sample if test is not done by the depository; and
- 7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the *Mycoplasma bovis* described in the specification as filed is the same as that deposited in the depository.

Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by Howard et al (*The Veterinary Record, October 17, 1987*).

Are
Claims 1-4 drawn to a vaccine composition comprising at least one inactivated or
attenuated *Mycoplasma bovis* biotype and a pharmaceutically acceptable excipient.

Howard et al disclose a quadrivalent vaccine containing the killed antigens of respiratory syncytial virus, parainfluenza virus type 3, *Mycoplasma bovis* and *Mycoplasma dispar* (see the Abstract). Howard et al disclose that the vaccines were formulated by suspending the antigens in phosphate buffered saline containing Quil A (Superfos) and 1% methiolate (see page 373). Characteristics such as the concentration of cells used in vaccines would be inherent in the vaccines of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's vaccine with vaccine of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the products of the prior art (i.e., that the vaccine of the prior art does not possess the same material structural

and functional characteristics of the claimed vaccine). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Howard et al (*The Veterinary Record, October 17, 1987*)

in view of Poumarat et al, (*Veterinary Microbiology, Volume 40, 1994, p. 305-321*).

Claims 5-12 are drawn to the vaccine composition of claim 1 wherein the *Mycoplasma bovis* bacteria is selected from the group consisting of a biotype A *Mycoplasma bovis* isolate, a biotype B *Mycoplasma bovis* isolate, a biotype C *Mycoplasma bovis* isolate, and combinations thereof.

Howard et al disclose a quadrivalent vaccine containing the killed antigens of respiratory syncytial virus, parainfluenza virus type 3, *Mycoplasma bovis* and *Mycoplasma dispar* (see the Abstract). Howard et al disclose that the vaccines were formulated by suspending the antigens in phosphate buffered saline containing Quil A (Superfos) and 1% methiolate (see page 373).

Howard et al do not teach a biotype A, B, C *Mycoplasma bovis*.

Poumarat et al disclose Restriction endonuclease analysis (REA) with three enzymes *Sma*I, *Pst*I, and *Bam*I which were used to identify 13 different genomic groups (i.e. biotypes) among 37 *Mycoplasma bovis* strains (see the Abstract). Poumarat et al disclose 37 bovis strains studied ^{which} gave five different electrophoretic patterns with *Bam*HI, four with *Sma*I and five with *Pst*I (figure 1). Poumarat et al further disclose that based on the combination of the different electrophoretic profiles obtained with the three enzymes, the 37 strains could be classified in 13 genomic groups (table 2).

It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the *Mycoplasma bovis* isolates of Poumarat et al to the vaccine composition as taught by Howard et al because Poumarat et al teach that there is a marked intraspecies genomic heterogeneity among isolates of *Mycoplasma bovis* collected from different geographic origins and that antigenic variability must be taken into account in developing diagnostic and vaccination strategies (page 319).

Pertinent Prior Art

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (*Rawadi, Methods in Molecular Biology, Volume 104, p. 179-197, Al-Aubaidi et al, Cornell Vet., Volume 61, 1971, p. 490-518, Cox et al, Vaccine, Volume 15, Number 3, 1997 and Fitzgerald et al, U.S. Patent No. 5,968,525, published October 19, 1999*).

Status of Claims

6. No claims are allowed.

Conclusion

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.


Vanessa L. Ford
Biotechnology Patent Examiner
October 5, 2001


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